## REMARKS/ARGUMENTS

The Office Action mailed February 5, 2009has been received and carefully noted. Claims 61-68 and 79-84 were examined and rejected. Claims 1-60 and 69-78 have been previously cancelled.

Applicants amend no claims and submit additional claim 85 for consideration. Applicants submit that no new matter is added herein. Without limitation thereto, additional claim 85 is supported at least at FIG. 82 block 9675 and corresponding paragraph 442 of the application, which states "liquid (e.g., such as blood and/or a treatment agent) is allowed to perfuse from a location in the blood vessel proximal to the balloon to the region of interest" (e.g., see region of interest 996 distal to balloon 8810 as described at paragraph 439 and fig. 85).

Applicants respectfully request reconsideration of claims 61-68 and claims 79-84; and consideration of claim 85 in view of the following remarks.

### I. Claim Rejections – 35 U.S.C. § 112

Claim 61 is rejected under 35 U.S.C. § 112, first paragraph because "perfusing a blood and a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon," as required by claim 61 is allegedly not enabled.

Applicants respectfully disagree with the rejection above for at least the reason that those limitations are supported by original claim 61. It would be clear to a practitioner that "blood and/or treatment agent" at least describes, for example and without limitation thereto, "blood and treatment agent".

Applicants also disagree with the rejection above for at least the reason that, for example and without limitation thereto, in addition to the description above supporting additional claim 85, paragraph 451 describes and figures 82-85 show "blood and/or treatment agent may be allowed to perfuse between a location in the blood vessel proximal and distal to an occluding balloon by retracting or pulling back a guidewire disposed through a guidewire lumen extending past at least one hole in the exterior of the cannula proximal to the balloon to allow perfusion to a location distal to the balloon via a guidewire lumen opening in the distal end of the cannula." Thus, upon reading at least at FIGs. 82-85 and corresponding paragraphs 451-453, 456, and 458-462 of the application, a practitioner with knowledge in the art would understand that according

to some embodiments, for example and without limitation thereto, the occluded blood and treatment agent described in blocks 9650 and 9660 of Fig. 82 may be perfused (such as at block 9675) between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon," as required by claim 61. It would be clear to a practitioner that "blood and/or treatment agent" at least describes, for example and without limitation thereto, "blood and treatment agent".

Hence, for at least this additional reason, Applicants respectfully request withdrawal of the rejection above of claim 61.

## II. Claim Rejections – 35 U.S.C. § 102

Claims 61-66, 68 and 79-84 are rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent Publication No. 2002/0049402 to Peacock ("Peacock"). It is axiomatic that to be anticipated, every limitation of the claim must be disclosed in a single reference.

Applicants respectfully disagree with the rejection above for at least the reason that the cited reference does not disclose a method including inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest during the occlusion of the blood vessel; and perfusing a blood and a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by claim 61.

Peacock paragraph 71 describes that when valve (6) is open and valve (7) is closed, antegrade aortic blood flow is shunted into distal flow port (4), through the internal flow lumen, out intermediate flow port (5), and into a proximal region of the aorta located proximally of the external shunt valve (3). However, this does not describe perfusing a blood and a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by claim 61.

Next, Peacock paragraph 73 describes that cardioplegia delivery port (8) is located distally of external shunt valve (3) in order to locally delivery the cardioplegia agent to the left heart and isolate the cardioplegia agent delivered from systemic circulation. Thus, Peacock paragraph 73 does not describe, perfusing a blood and a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by claim 61.

Moreover, there is no disclosure in Peacock of combining the descriptions of paragraphs 71 and 73 as suggested in the anticipation rejection. Instead, Peacock teaches against such a combination by teaching that "the cardioplegia delivery port (8) is adapted to be positioned within the aortic root such that cardioplegia agent may be delivered to the heart via the coronary arteries stemming therefrom." Thus, Peacock does not disclose or teach perfusing a blood and a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon as required by claim 61.

On the other hand, for example, without limitation thereto, by perfusing blood and treatment agent during the occlusion of the blood vessel, embodiments described in the specification, for example, without limitation thereto provide the unexpected benefits of: (1) allowing drugs to be injected distal to the balloon, and then allowing the blood and drugs to be perfused using the ports located distal and proximal to the balloon to allow blood flow and avoid ischemia (see at least para. 458 of the application); (2) so that the drugs can be injected, and the blood and drugs can be perfused repeatedly, while the balloon stays inflated (e.g., does not need to be deflated and reinflated) to occlude the blood vessel (see at least FIG. 82-85; paras. 447 and 461 of the application; and claims 63 and 65); (3) allowing the amount of blood and treatment agent perfused to be controlled over a desirable range, such as by retracting and extending a guide wire in a lumen (see at least FIG. 88; paras. 459-462 of the application; and claims 64 and 66); and (4) allowing blood and treatment agent to be perfused from a location in the blood vessel proximal to the balloon into the region of interest distal to the balloon (see at least FIG. 82; paragraph 442; and claim 85). However, Peacock does not contemplate or enable such benefits.

Next, in addition to the dependence upon claim 61, Applicants respectfully disagree with the rejection of claim 63 for at least the reason that Peacock does not disclose a method wherein inflating includes inflating the balloon for a first period of time to occlude the blood vessel for the first period of time and perfusing includes deflating the balloon for a second period of time; and at least one more repetition of inflating, infusing, and deflating as required by claim 63. Peacock only describes using valve (6) and valve (7) to shunt antegrade aortic blood flow into distal flow port (4); and locally delivery the cardioplegia agent to the left heart (see paragraphs 71-73). Thus, the Patent Office has not identified and Applicants are unable to identify any disclosure in Peacock of the above noted limitations of claim 63. Hence, Applicants respectfully

request the Patent Office withdraw the rejection of claim 63 for this additional reason.

Moreover, in addition to the dependence upon allowable base claim 61, Applicants respectfully disagree with the rejection of claim 64 for at least the reason that Peacock does not disclose or enable retracting a guidewire from a location distal to at least on hole to a location proximal to the at least one hole to cause profusion through the at least one hole as required by claim 64. However, the Patent Office has not identified and Applicants are unable to find any disclosure or enablement of a guidewire of Peacock being retracted to cause profusion through at least one hole in the exterior surface of a canula as required by claim 64. Instead, Peacock only describes using valve (6) and valve (7) to shunt antegrade aortic blood flow into distal flow port (4); and locally delivery the cardioplegia agent to the left heart (see paragraphs 71-73). Hence, for at least this additional reason, Applicants respectfully request the Patent Office withdraw the rejection of claim 64.

Furthermore, in addition to its dependence upon allowable base claim 61, Applicants respectfully disagree with the rejection of claim 66 for at least the reason that Peacock does not disclose or enable retracting a distal end of a guidewire to control an amount of a blood and treatment agent profusion, as required by claim 66. Peacock only describes using valve (6) and valve (7) to shunt antegrade aortic blood flow into distal flow port (4); and locally delivery the cardioplegia agent to the left heart (see paragraphs 71-73). Hence, for at least this additional reason, Applicants respectfully request that the Patent Office withdraw the rejection of claim 66.

Next, in addition to the dependence upon claim 61, Applicants respectfully disagree with the rejection of claim 82 for at least the reason that Peacock does not disclose or enable retracting a distal end of a guidewire to a location proximal to at least one hole to allow profusion, as required by claim 83. An argument analogous to the one above for claim 64 applies here as well. Hence, for at least this additional reason, Applicants respectfully request withdrawal of the rejection above of claim 83.

## III. Claim Rejections – 35 U.S.C. § 103

Claims 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peacock in view of U.S. Patent No. 6,805,860 to Alt (Alt). For a claim to be obvious, each limitation of the claim must be taught or suggested by at least one properly combined reference. Furthermore, the combination of elements must be "more than a predictable use of prior art elements according to

their established functions." (see KSR International Company v. Teleflex Inc., No. 04-1350 (Supreme Court, April 30, 2007)).

Applicants respectfully disagree with the rejection above for at least the reason that Alt does not cure the deficiencies of Peacock noted above for claim 61, from which the above noted claim depends.

Alt teaches using autologis adult stem cells which are derived from the same patient to replace necrotic tissue of a failing organ of that patient, such as a heart after an MI (see col. 5, line 52 through col. 6, line 32). However, the Patent Office has not identified and Applicants are unable to find any teaching in Alt of the above-noted limitations of claim 61.

## IV. Dependent Claims

Any dependent claims not mentioned above are submitted as being patentable for at least the reasons provided in support of their base claim, as well as additional limitations of each dependent claim.

Hence, Applicants respectfully request the Patent Office withdraw all the rejections above.

## V. Additional Claim 85

Applicants submit that in addition to the dependence upon claim 61, additional claim 85 is patentable for at least the reasons provided in support of its base claim, as well as additional limitations of each dependent claim.

## CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes a telephone conference would be useful in moving the case forward, he is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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**CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being submitted to the United States Patent and Trademark Office electronically via EFS Web on the date shown below.

Jessica Huester 5/5/09

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